DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 5, 2016

Overmed S.r.l.
Davide Pizzamiglio
Legal Representative
Via Lucania 23 Buccinasco
Milan, 20090
ITALY

Re: K143596
Trade/Device Name: MINIARS Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: December 3, 2015
Received: December 24, 2015

Dear Mr. Pizzamiglio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143596

Device Name

MINIARS Screws

Indications for Use *(Describe)*

MINIARS screw system is intended for fixation of intra-articular and extra-articular fractures, non-union and osteotomies of small bones and small bone fragments. Some examples include:
- arthrodesis of small joints (foot and hand surgery);
- intra-articular metatarsal and metacarpal fractures;
- osteotomies for hallux valgus treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Name of Submitter	Overmed S.r.l. Via Lucania 23 20090 Buccinasco (MI) Italy
Name of Manufacurer	Overmed S.r.l. Via Lucania 23 20090 Buccinasco (MI) Italy
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Trade Name	MINIARS Screws
Device Common name	MINIARS Screws
Device Classification	Class II
Review Panel	Orthopedic
Product Code	HWC
CFR Section	21CFR888.3040 "Smooth or threaded metallic bone fixation fastener"

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K143596 Date Prepared: February 04, 2016

5.1 Identification of Predicate Devices:

Predicate Device	510(k) Number	Product Code
SBI AutoFix™ System	K052576	HWC
Synthes 3.0 mm Headless Compression Screws	K050636	HWC

5.2 Description:

The following is a brief description of the Overmed MINIARS Screws.

MINIARS screw system is intended for fixation of intra-articular and extra-articular fractures, non-union and osteotomies of small bones and small bone fragments.
MINIARS screws are implants that will be in contact with body tissues for more than 30 days. Instrumentation used to assist in their implantation will be in temporary contact (inferior to 24 hours) with body tissues.
The MINIARS screws are intended for single use only.
The implant is a solid, one piece, cannulated and partially thread shaped design.
MINIARS screws are available in two different external thread diameters: 2.2 mm e 2.6 mm.
MINIARS screws are available in a range of lengths from 10mm to 30mm.
All the screws sizes available are described in table 5.1.
The screws are partially threaded: the proximal and distal parts are threaded while the middle part is cylindrical, as visible in figure 5.1.
The thread shape has been designed to facilitate the compression of the bone fragments and the hold in cancellous bone thanks to the particular profile design: the wide thread pitch of the distal part penetrates in bone tissue faster than the thread of the proximal part, reducing and compressing the fracture through screw advance.
Distal thread presents self-drilled and self-tapping grooves.

Fig. 5.1 MINIARS Screw

The screws present a hexagonal torx 6 head which is conforming to ISO 10664 standard.

All the MINIARS screws are supplied in a sterile state (beta rays); the single screw is packed into a double blister which allows the usage in surgery.

The MINIARS Screws are made of Titanium Alloy (Ti6Al4V ELI gr. 5) and is available in the range of sizes reported in the table below.

Table 5.1 MINIARS Screw sizes

MINIARS Screw Diameter	Code (STERILE)	Length [mm]
Ø2.2	A0502210	10
	A0502212	12
	A0502214	14
	A0502216	16
	A0502218	18
	A0502220	20
	A0502222	22
	A0502224	24
	A0502226	26
	A0502228	28
	A0502230	30
Ø2.6	A0502610	10
	A0502612	12
	A0502614	14
	A0502616	16
	A0502618	18
	A0502620	20
	A0502622	22
	A0502624	24
	A0502626	26
	A0502628	28
	A0502630	30

5.3 Indications for Use:

MINIARS screw system is intended for fixation of intra-articular and extra-articular fractures, non-union and osteotomies of small bones and small bone fragments. Some examples include:
- arthrodesis of small joints (foot and hand surgery);
- intra-articular metatarsal and metacarpal fractures;
- osteotomies for hallux valgus treatment.

5.4 Performance Testing:

To support the performance characteristics of MINIARS screws we conducted the following tests:

- FEA analysis, to study the maximum stress in the subject screw under a 300Ncm torsional load;
- Pullout test, to measure the strength to be employed in order to extract a screw totally inserted into the bone;
- Maximum screw torque test, to measure the maximum torque bearable before the screw failure;
- Bending test, to measure the yield moment reached after a 2.5 mm displacement.
- Dimensional comparison with other 510(k) cannulated screws

The results demonstrated that the performance of the subject device is substantially equivalent to the predicate devices.

5.5 Substantial equivalence:

Documentation is provided which demonstrates the Overmed MINIARS Screws to be substantially equivalent to other legally marketed devices. All the devices are “Smooth or threaded metallic bone fixation fastener” as defined in 21 CFR 888.3040, furthermore, the size, shape and materials for the subject devices are comparable to the predicate devices.

5.6 Conclusion:

Based upon the similarities in design, materials, performance testing and intended uses, the Overmed MINIARS Screw is substantially equivalent to the predicate devices.